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In the
Supreme Court of the United States

ALLIANCE SECURITY PRODUCTS, INC. and
ALLIANCE SECURITY INTERNATIONAL, LLC,

Petitioners,

- v. -

FLEMING AND COMPANY, PHARMACEUTICALS,

Respondent.

PETITION FOR WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

PETITION FOR WRIT OF CERTIORARI

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QUESTION PRESENTED

This case raises an important federal issue regarding when a federal court should grant summary judgment under Federal Rule 56 of the Federal Rules of Civil Procedure, an issue not addressed by this Court since 1986. In this case, the courts below granted and affirmed summary judgment in favor of respondent on the basis that the valuable idea for a new drug product confidentially shared with respondent was not sufficiently novel, despite the fact that the federal government (the FDA) awarded the drug Orphan Drug status under 21 U.S.C.S. § 360aa *et seq*. and proceeded to stockpile millions of dollars worth of the drug in the event of a terrorist attack on a nuclear facility. The district and circuit courts ignored these probative facts entirely, which demonstrated that the drug idea was new to defendant and the drug product industry. Without the protection of the copyright or patent acts, inventors of useful ideas are seemingly without recourse if material facts can be ignored by courts disposing of cases under Rule 56. The question therefore is whether this Court should reassess the courts' powers under Rule 56, and specifically:

1. Whether a court may properly find that a product idea lacks "novelty" on a motion for summary judgment where material issues of fact exist as to novelty, given the fact that the FDA recognized the product idea as a newly developed drug worthy of Orphan Drug designation.

LIST OF THE PARTIES TO THIS PROCEEDING

The parties are all listed in the caption.

STATEMENT PURSUANT TO RULE 29.6

Alliance Security Products, Inc. and Alliance Security International, LLC (collectively, "Alliance"), have no parent corporations and no publicly held corporation owns 10% or more of its stock.

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Appendix A29–A41: The Orphan Drug Act, 21 U.S.C.S. § 360aa *et seq*.

PETITION FOR WRIT OF CERTIORARI

Petitioners respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Second Circuit.

OPINIONS BELOW

The opinion of the Second Circuit, No. 07-0526-cv, was entered on July 29, 2008 and is an unreported opinion, but can be found on Lexis at 2008 U.S. App. LEXIS 16098. It is reprinted in Appendix A to this petition. The opinion of the United States District Court for the Southern District of New York, decided January 26, 2007, is reported at 471 F. Supp. 2d 452 (S.D.N.Y. 2007) and is reprinted in Appendix A to this petition.

STATEMENT OF JURISDICTION

1. The judgment of the United States Court of Appeals for the Second Circuit ("Second Circuit") sought to be reviewed was entered on July 29, 2008.

2. The statutory provision which confers jurisdiction on the Supreme Court to review a judgment of a circuit court of appeals on a writ of certiorari is 28 U.S.C. § 1254 (1).

STATUTORY PROVISIONS INVOLVED

This case involves Rules 1 and 56 of the Federal Rules of Civil Procedure, and 21 U.S.C.S. § 360aa *et seq*. (the Orphan Drug Act). The text of Rules 1 and 56 are set forth below, and the text of the Orphan Drug Act appears in Appendix A29–A41:

Federal Rule of Civil Procedure 1.

These rules govern the procedure in all civil actions and proceedings in the United States district courts, except as stated in Rule 81. They should be construed and administered to secure the just, speedy, and inexpensive determination of every action and proceeding.

Federal Rule of Civil Procedure 56.

(a) By a Claiming Party. A party claiming relief may move, with or without supporting affidavits, for summary judgment on all or part of the claim. The motion may be filed at any time after:

(1) 20 days have passed from commencement of the action; or

(2) the opposing party serves a motion for summary judgment.

(b) By a Defending Party. A party against whom relief is sought may move at any time, with or without supporting affidavits, for summary judgment on all or part of the claim.

(c) Serving the Motion; Proceedings. The motion must be served at least 10 days before the day set for the hearing. An opposing party may serve opposing affidavits before the hearing day. The judgment sought should be rendered if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law.

21 U.S.C.S. § 360aa et seq. (the Orphan Drug Act)

The text of the Orphan Drug Act appears in Appendix A29–A41.

STATEMENT OF THE CASE

Basis for Jurisdiction in the First Instance

The United States District Court for the Southern District of New York ("District Court"), pursuant to 28 U.S.C. § 1332, exercised subject matter jurisdiction over petitioners' claims because the parties were citizens of different states and the amount in controversy exceeds the sum of $75,000.

Factual Background

Petitioner Alliance, pursuant to a fully executed non-disclosure agreement between it and Respondent Fleming and Company, Pharmaceuticals ("Fleming"), revealed a new product concept developed by Alliance for the marketing, manufacturing and selling of an over-the-counter ("OTC"), liquid pediatric potassium iodide solution, in a palatable base with graduated pediatric dropper markings and child safety cap, to be approved by the United States Food and Drug Administration ("FDA") and to be used in emergency response to radiological events producing radioiodides, such as a terrorist attack or serious accident at a nuclear facility (the "Product").

Just days after Alliance's confidential presentation to Fleming, Fleming secretly took the information it learned from Alliance for its own use and developed the very same product revealed to Fleming by Alliance. The record evidence demonstrates that

prior to meeting with Alliance, Fleming never sought to develop a pediatric potassium iodide liquid solution for use as a thyroid protectant in the event of a nuclear emergency, but that after meeting with Alliance, Fleming began to covertly do so on its own while, at the same time, Fleming negotiated with Alliance to be its exclusive manufacturer of Alliance's product. Simply put, if not for Fleming's exposure to Alliance's business plan and concept for the Product, neither Fleming nor the public would have had this vital new liquid potassium iodide product.

Without affording Alliance all reasonable inferences, as it must on a motion for summary judgment, the District Court erroneously concluded that nothing in Alliance's business model for the Product, or the Product itself, was novel either to Fleming or to the public in general. The Court of Appeals for the Second Circuit affirmed the District Court's decision for the same reason of lack of novelty. However, there is no dispute that prior to Fleming's misappropriation of Alliance's Product and business model, (1) despite a market in which there were nine manufacturers selling potassium iodide products as radioiodine protectants, there was no product like the one Alliance developed on the market, (2) Fleming's own documents and public statements acknowledge that the Product was the first of its kind, and, perhaps most importantly, (3) the federal government granted Fleming Orphan Drug status for the Product. These material facts, among others, which provide support that the Product was novel, were ignored by both the District Court and the Court of Appeals.

It is unclear whether the novelty of an idea is a question of fact or a mixed question of fact and law, as courts have differed on this issue. *See, e.g., Phillips v. Avis, Inc.*, 1995 U.S. Dist. LEXIS 9735, No. 95 C 1566, 1995 WL 417587, at *2 (N.D. Ill. July 13, 1995) (holding that determination of whether a trade secret is "novel" is a mixed question of fact and law); *All Pro Sports Camp, Inc. v. Walt Disney Co.*, 727 So. 2d 363, 368 (Fla. Dist. Ct. App. 1999) (holding that whether an idea is novel is a factual question); *G.D. Searle & Co. v. Philips-Miller & Assocs., Inc.*, 836 F. Supp. 520, 527 (N.D. Ill. 1993) (same). As explained below, *Nadel v. Play-By-Play Toys & Novelties, Inc.*, 208 F.3d 368, 378 (2d Cir. 2000) seems to indicate that the question of whether an idea is sufficiently novel to be protected is indeed a factual determination, and while a court can grant summary judgment in those cases where no reasonable finder of fact could find novelty, a court must not do so if material facts underlying the issue of novelty are in dispute. *Nadel*, 208 F.3d at 380. In reaching their conclusion that Alliance's Product was not sufficiently novel, the district and circuit courts misapplied the summary judgment standard set forth in the trilogy of *Celotex Corp. v. Catrett*, 477 US 317 (1986), *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986), and *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574 (1986), and abused Federal Rule of Civil Procedure 56 by failing to consider material facts which raise a triable issue as to novelty based on the test for novelty set forth in *Nadel*.

Indeed, just days after Alliance's presentation, Fleming, which had been in existence for decades and had never marketed potassium iodide other than

as a mucolytic agent sold in bulk containers to pharmacies and hospitals, secretly took the information it learned from Alliance for its own use and developed the very same product developed and revealed to Fleming by Alliance. The record of evidence demonstrates that Fleming took Alliance's valuable idea for the Product, submitted an Abbreviated New Drug application to the Food and Drug Administration, and received an Orphan Drug Designation for the product pursuant to 21 U.S.C. § 360cc(a), signaling that even the federal government believed the product to be novel. Simply put, if not for Fleming's exposure to Alliance's Business Plan and concept for the Product, neither Fleming nor the public would have had this new and important liquid potassium iodide product which protects the nation's children from terrorist attacks on nuclear facilities.

Prior to the solution Alliance offered, the market was bereft of child-friendly products that could block thyroid radiation exposure in children, the most susceptible population to this risk. Prior to Alliance's Product (put into commerce by Fleming), the FDA guidelines for administering potassium iodide to children or others who could not swallow a pill were to apportion a 65 mg or 130 mg potassium iodide tablet to a certain size depending on the child's age, grind the tablet in a bowl, add water and flavoring to mask the unpleasant taste, and refrigerate the mixture, which could last for only seven days. *See* Home Preparation Procedure for Emergency Administration of Potassium Iodide Tablets to Infants and Children Using 130 Milligram (mg) Tablets, http://www.fda.gov/cder/drugprepare/kiprep130mg.htm (last visited October 23, 2008).

Alliance's pediatric physician saw the impracticality of the FDA recommendation, and via its market research, Alliance discovered that many consumers were concerned about the FDA's recommendation for administering potassium iodide to children. For example, apportioning the tablet for correct dosing before crushing the pill in the midst of a nuclear emergency would be very difficult. In addition, Alliance's consumer studies showed concerns about the potency and stability of home mixtures, the taste and the impracticality of administering potassium iodide to children in daycare facilities or schools. These points were shared with Fleming during the confidential presentation.

Procedural Background

Petitioners in this case asserted claims for breach of contract, misappropriation of idea, unfair competition, accounting, conversion, breach of implied in fact contract/unjust enrichment and misappropriation of trade secret, all under New York state law. All causes of action were based upon Fleming's unauthorized use of market research, a business model and a new product concept developed by Alliance for the marketing, manufacturing and selling of an over-the-counter ("OTC"), liquid pediatric potassium iodide solution, in a palatable base with graduated pediatric dropper markings and child safety cap, to be approved by the United States Food and Drug Administration ("FDA") and to be used in emergency response to radiological events producing radioiodides, such as a terrorist attack on a nuclear facility (the "Product").

Fleming moved for summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure. The District Court granted Fleming's motion in its entirety, dismissing Alliance's complaint. Specifically, the District Court found that the Product was not sufficiently novel to receive protection.

By Notice of Appeal timely filed on February 13, 2007, pursuant to Federal Rule of Appellate Procedure 4(a)(1), Alliance appealed from the final judgment of the District Court. The Second Circuit had appellate jurisdiction over the appeal pursuant to 28 U.S.C. § 1291, as an appeal as of right from a final judgment of a United States district court. The Second Circuit rendered a decision on July 29 2008 and affirmed the District Court's decision.

REASONS FOR GRANTING THE PETITION

I. THE DECISION INHIBITS THE CREATION OF USEFUL PRODUCTS BY ALLOWING GRANTS OF SUMMARY JUDGMENT WHERE MATERIAL ISSUES OF FACT EXIST AS TO WHETHER AN IDEA IS NOVEL.

The Second Circuit affirmed summary judgment against petitioner despite its determination that it was likely that it was Fleming's meeting with Alliance "that opened Fleming's eyes to the possibilities of the strategy it had put on hold." (App. A6).

In the Second Circuit, *Nadel v. Play-By-Play Toys & Novelties, Inc.*, 208 F.3d 368 (2d Cir. 2000), concluded that novelty of a concept depends on several factors, including: "the idea's specificity or generality (is it a generic concept or one of specific application?), its commonality (how many people know of this idea?), its uniqueness (how different is this idea from generally known ideas?), and its commercial availability (how widespread is the idea's use in the industry?)" *Id.* at 378. Importantly, the *Nadel* Court left open the idea that it would be legally permissible to conclude that an idea was novel based on the combination of existing elements. Indeed, in *Victor G. Reiling Assocs. & Design Innovation, Inc. v. Fisher-Price, Inc.*, 450 F. Supp. 2d 175, 180 (D. Conn., 2006), a case relied upon by the District Court in this case, the district court in Connecticut aptly recognized that novelty can exist through a combination of known elements that are not themselves novel. *Victor Reiling Assocs. & Design Innovation, Inc.*, 450 F. Supp. 2d at 180.

There, the court rejected the defendant's argument — made on a motion for judgment as a matter of law following a jury trial resulting in a verdict against the defendant on misappropriation and unfair competition claims — that a combination of non-novel elements, even if never before found together in the same product, can never be novel. *Id.* at 180-81. Relying on *Nadel*, the court stated:

> By declining to comment on the District Court's discussion of the combination of existing elements, and remanding for consideration based on the novelty standard articulated, the Second Circuit [in *Nadel*] suggested that it would be legally permissible for the district court to conclude that such a combination was in fact novel. This comports with the purpose of the novelty requirement as described in *Nadel* — while there is no protection for that which is 'free and available to all,' an innovative idea to combine certain existing elements may be novel because that idea may not be in the public domain.

Id. at 180; *see also McGhan v. Ebersol*, 608 F. Supp. 277, 284 (S.D.N.Y. 1985) (recognizing that the fact that a plaintiff's idea embodies elements long in use does not itself negate originality or novelty).

While the concept of novelty is steeped in the common law, it should not indiscriminately derail cases from litigation track. Indeed, Professor Arthur R. Miller has noted that courts have used the concept of novelty "not because it is particularly easy to administer early in litigation, but rather because in practice it dispenses with close cases without burdening factfinders with the cumbersome task of

sifting through evidence." Arthur R. Miller, *Common Law Protection for Products of the Mind: An "Idea" Whose Time Has Come*, 119 Harv. L. Rev. 703, 730 (2006). This use, or misuse, of the concept of "novelty" has the untoward effect of causing the dismissal of meritorious idea cases without a public fact-finding hearing and a chance for the idea developer and his experts to be heard in support of the protection of the idea. Here, for instance, should not a fact-finder have the opportunity to ponder why the FDA would grant specific statutory protection to the idea were it not novel and of great value to some segment of the public?

The evidence adduced on the summary judgment motion in this case demonstrates that Alliance presented Fleming with a specific and unique concept for the Product in the Business Plan. Application of the novelty factors set forth in *Nadel* and its progeny to the facts of this case yields but one conclusion: material issues of fact exist concerning whether the Product was novel and the Business Plan contained confidential information unknown to Fleming or the public at the time.

As mentioned in the factual background, some cases have held that novelty is a question of fact. *See All Pro Sports Camp, Inc. v. Walt Disney Co.*, 727 So. 2d at 368; *G.D. Searle & Co. v. Philips-Miller & Assocs., Inc.*, 836 F. Supp. 520, 527 (N.D. Ill. 1993). Indeed, the *Nadel* court presented a factual test for the determination of when an idea is sufficiently novel to warrant protection. Following the *Nadel* test, Alliance, in opposition to Fleming's summary judgment motion, submitted evidence demonstrating that: (1) the misappropriated idea for the Product

was specific; (2) the idea for the product was unknown and unique — indeed, prior to Fleming's misappropriation of the Product, while there were nine companies in the industry manufacturing potassium iodide in pill form, none thought to manufacture or market liquid potassium iodide for children; (3) the record is replete with evidence that the idea for the product was not known to the public or to Fleming; and (4) prior to Fleming's misappropriation, the Product was not commercially available. *Nadel,* 208 F.3d at 378. Perhaps the best example of the Product's lack of commercial availability prior to Fleming's misappropriation of the same is the FDA's award of Orphan Drug Status[1] to the Product. The evidence even demonstrated that Fleming's application for the status recognized the current unavailability of a potassium iodide formulation that is ready to dose young children, which represents a serious obstacle to proper patient care. Without the valuable idea Alliance shared with Fleming as part of a contractual arrangement, the young citizenry of this country would have had no reasonable way to obtain an antidote for radioactive iodine exposure, and the only reason they have that protection today is because of the Alliance idea that was stolen by Fleming.

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[1] The Orphan Drug Act was enacted in order to provide drug manufacturers with incentives to develop drugs for the treatment of rare diseases or disorders that affect only small patient populations. In pursuit of this objective, Congress offered research assistance, grants, and tax incentives to companies that undertake development of orphan drugs. In addition, Congress provided for seven years of market exclusivity for approved orphan drugs. *See* Appendix A29–A41.

II. THIS CASE PRESENTS A PRIME VEHICLE FOR THE 1986 SUMMARY JUDGMENT TRILOGY OF CASES TO BE RE-EXAMINED AND REFINED.

One of the persistent issues confronting District and Circuit courts is where to draw the line in summary judgment cases where there are mixed questions of law and fact. Since 1986, this line has become increasingly blurred. As Professor Arthur R. Miller astutely observes in his article *The Pretrial Rush to Judgment: Are the "Litigation Explosion," "Liability Crisis," and Efficiency Cliches Eroding Our Day in Court and Jury Trial Commitments?*, 78 N.Y.U.L. REV. 982 (2003), the Supreme Court 'trilogy' of *Matsushita Electric Industrial Co. v. Zenith Radio Corp.*, *Anderson v. Liberty Lobby, Inc.*, and *Celotex Corp. v. Catrett* "transformed summary judgment from an infrequently granted procedural device to a powerful tool for the early resolution of litigation." *Id.* at 984. "Since then, federal courts have employed summary judgment . . . in cases that before the trilogy would have proceeded to trial . . ." *Id.*

Judges and legal scholars alike have recognized the need for a reassessment of the federal summary judgment standard. *See, e.g., Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, 07-cv-02762, 2008 U.S. Dist. LEXIS 47189, at *13 (D.N.J. June 12, 2008) ("'[O]veruse' of summary judgment can prejudice the litigant who has limited resources to pursue its claim or defense."); Suja A. Thomas, *The Unconstitutionality of Summary Judgment: A Status Report*, 93 Iowa L. Rev. 1613 (2008); John Bronsteen, *Against Summary Judgment*, 75 Geo. Wash. L. Rev.

522, 531 (2007) ("The dominant theme of civil procedure scholarship over the past twenty-five years has been how rare trials have become."); Miller, 78 N.Y.U.L. REV. at 1064 ("Some courts in the post-trilogy years appear to have encroached on the factfinder's role in deciding Rule 56 motions."). For example, in *United States v. Luisi*, No. 99-10218, 2008 U.S. Dist. LEXIS 56145 (D. Mass. July 25, 2008), the Massachusetts district court states that "statistics suggest that district courts and appellate courts fail to afford jury verdicts the proper degree of deference and that many trial courts simply overuse summary judgment." *See id.* at *33. Indeed, that court observed last year that since the trilogy, federal courts "overuse summary judgment as a case management tool." *In re One Star Class Sloop Sailboat*, 517 F. Supp. 2d 546, 555 (D. Mass. 2007). The Court quotes Judge Richard S. Arnold, stating that he "cuts directly to the bone" in the following comment:

> I think in the 20 years since I was a district court judge, we've seen a tremendous increase in volume, tremendous pressure to decide cases without thinking very much about them, tremendous pressure to avoid deciding cases. I mean, some judges will do almost anything to avoid deciding a case on the merits and find some procedural reason to get rid of it, coerce the parties into settling or whatever it might be.

Id. at 555 (quoting Judge Richard S. Arnold, *Mr. Justice Brennan and the Little Case*, 32 LOY. L.A. L. REV. 663, 670 (1999). *See also, e.g., Doe v. Abington Friends School*, 480 F.3d 252, 258 (3d Cir. 2007) ("Since the Supreme Court removed the [summary]

judgment procedure from disfavored status in the 1980s, some have opined that the pendulum has swung too far in the opposite direction."); Patricia M. Wald, *Summary Judgment at Sixty*, 76 TEX. L. REV. 1897 (1998). In her article, Judge Wald points out that:

> In calendar year 1996, the civil docket in the District Court for the District of Columbia indicated that forty-two percent of terminations were by dismissal; nineteen percent were settled before trial (none during trial); three percent were terminated by trial; twenty-two percent were terminated by summary judgment; and seven percent were transferred to other courts. In the first three quarters of 1997, the rate for summary judgments stayed at twenty-two percent. These District of Columbia statistics bear out the generalized prediction that we are approaching a time when a civil trial will be thought of as a 'pathological event.' And despite the high profile that 'alternative dispute resolution' has enjoyed in the past decade and a half, summary judgment may in fact be the more commonly used mode of disposition on the merits, outnumbering settlement by court-annexed arbitration, mediation, early neutral evaluation, and other settlement techniques.

Id. at 1915. In sum, the lengthy discourse on the overuse of summary judgment standard following the *Matsushita Electric Industrial Co. v. Zenith Radio Corp.*, *Anderson v. Liberty Lobby, Inc.*, and *Celotex Corp. v. Catrett* trilogy gives ample support to Petitioner's belief that the Rule 56 standard is ripe for reevaluation.

Alliance is one of the unfortunate casualties of the lack of clarity inherent in the trilogy formulation, because this Court's mandate to only grant summary judgment where there is "no genuine issue of material fact" was not followed. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986). If one believes that "novelty" is an issue of fact and law, and it would appear that this is what the *Nadel* case and the others cited at pages 5-6, *supra*, hold, it is clear that the courts below crossed the line and impinged on the prerogatives of a jury in dismissing this case without a trial.

The record below contains abundant — and material — evidence that would support a finding under the factors set forth in *Nadel* that the Product was novel to the public as well as novel to Fleming.[2] The evidence would have allowed a reasonable fact-finder to conclude that Alliance's Product was worthy of protection by the courts and unlawfully misappropriated by Fleming.

The evidence features the plain and unarguable fact that the federal government saw fit to award the product Orphan Drug status: this in and of itself should have been sufficient to create a genuine issue of fact as to novelty. However, also included in the record was probative and largely undisputed evidence that:

(1) Fleming had been in existence for decades but did not create the product at issue until immediately after it met with Alliance;

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[2] The Joint Appendix filed below fills six volumes that are replete with affidavits, documents and deposition testimony establishing the facts that are described in this Petition.

(2) when Alliance's CEO discussed the concept for the Product with Fleming, Fleming repeatedly told him that it did not see a need for the Product, and asserted that it did not believe that the United States government would even admit that a real threat of nuclear attack existed, and therefore would not willing to invest in the Product;

(3) once Alliance convinced Fleming of the market for the Product and prior to Fleming's misappropriation, the parties exchanged numerous telephone calls, emails and drafts of agreements for an exclusive distribution agreement and, ultimately, the parties reached agreement on all key business terms, except for pricing, but left open further negotiations;

(4) there was no FDA-approved potassium iodide pediatric liquid solution on the market prior to the development of the Alliance idea for the product, despite the existence of nine potassium iodide pill manufacturers that were competing for sales in the United States and worldwide.[3]

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[3] As mentioned by Professor Miller, *Anderson v. Liberty Lobby* explained that the Rule 56 standard was to mirror the governing rule under Rule 50(a) for a directed verdict which requires a trial judge to "direct a verdict if, under the governing law, there can be but one reasonable conclusion as to the verdict." *See* Miller, 78 N.Y.U.L. REV. at 1036-37 (quoting *Anderson v. Liberty Lobby*, 477 U.S. at 250.). The recited facts would readily pass muster to support a verdict in favor of Alliance on the novelty issue yet this case was dismissed perhaps in part because this standard lacks clarity.

In short, what the courts below require is guidance from the Court regarding where the summary judgment line is to be drawn in cases of mixed law and fact, a line that was not addressed in the trilogy and that continues to perplex practitioners and courts with regularity.

The harm resulting from allowing this line to remain indistinct is that meritorious cases like that brought by Alliance will continue to be dismissed. The harm to this country due to the lack of protection of worthy ideas is immeasurable. It cannot be ascertained how many cases of a similar nature have never been brought or reported in the law reports. Conceivers of ideas are afraid to make worthwhile disclosures, even under the umbrella of a non-disclosure agreement as was the case here, because they cannot trust that their ideas will receive protection from the courts.

A review of the Rule 56(c) summary judgment standard, and in particular how (and if) courts should decide the mixed fact and law question of novelty in idea cases is the opportunity presented by this Petition. Without specific guidance resolving the uncertainty that is extant with respect to the protection of new ideas, our society risks losing valuable contributions from idea developers who are fearful that their creations will not be protected. Given the current state of affairs, one would not expect our children to have the benefit of stockpiles of palatable liquid potassium iodide in the event of a nuclear catastrophe. We submit that this uncertainty should be rectified.

CONCLUSION

Petitioners respectfully request that this Court grant this petition for certiorari to review the question that would be presented on this appeal.

Dated: October 27, 2008

Respectfully submitted,

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07-0526-cv
Alliance Security Prods., Inc. v. Fleming & Co.

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

SUMMARY ORDER

RULINGS BY SUMMARY ORDER DO NOT HAVE PRECEDENTIAL EFFECT. CITATION TO SUMMARY ORDERS FILED AFTER JANUARY 1, 2007, IS PERMITTED AND IS GOVERNED BY THIS COURT'S LOCAL RULE 32.1 AND FEDERAL RULE OF APPELLATE PROCEDURE 32.1. IN A BRIEF OR OTHER PAPER IN WHICH A LITIGANT CITES A SUMMARY ORDER, IN EACH PARAGRAPH IN WHICH A CITATION APPEARS, AT LEAST ONE CITATION MUST EITHER BE TO THE FEDERAL APPENDIX OR BE ACCOMPANIED BY THE NOTATION: "(SUMMARY ORDER)." A PARTY CITING A SUMMARY ORDER MUST SERVE A COPY OF THAT SUMMARY ORDER TOGETHER WITH THE PAPER IN WHICH THE SUMMARY ORDER IS CITED ON ANY PARTY NOT REPRESENTED BY COUNSEL UNLESS THE SUMMARY ORDER IS AVAILABLE IN AN ELECTRONIC DATABASE WHICH IS PUBLICLY ACCESSIBLE WITHOUT PAYMENT OF FEE (SUCH AS THE DATABASE AVAILABLE AT HTTP://WWW.CA2.USCOURTS.GOV/). IF NO COPY IS SERVED BY REASON OF THE AVAILABILITY OF THE ORDER ON SUCH A DATABASE, THE CITATION MUST INCLUDE REFERENCE TO THAT DATABASE AND THE DOCKET NUMBER OF THE CASE IN WHICH THE ORDER WAS ENTERED.

At a stated term of the United States Court of Appeals for the Second Circuit, held at the Daniel Patrick Moynihan Courthouse, 500 Pearl Street, in the City of New York, on the 29th day of July, two thousand eight.

PRESENT: HON. ROBERT A. KATZMANN,
HON. DEBRA ANN LIVINGSTON,
Circuit Judges,
HON. ERIC N. VITALIANO,
District Judge.[1]

UNITED STATES COURT OF APPEALS
FILED
JUL 29 2008
Catherine O'Hagan Wolfe, Clerk
SECOND CIRCUIT

ALLIANCE SECURITY PRODUCTS, INC. and ALLIANCE SECURITY INTERNATIONAL, LLC,

Plaintiffs-Appellants,

07-0526-cv

- v. -

FLEMING AND COMPANY, PHARMACEUTICALS,

Defendant-Appellee.

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[1] The Honorable Eric N. Vitaliano of the United States District Court for the Eastern District of New York, sitting by designation.

For Plaintiffs-Appellants: FRANK H. PENSKI (Erika J. Duthiers, Tamar Y. Duvdevani, *of counsel*), Nixon Peabody LLP, New York, NY.

For Defendant-Appellee: WILLIAM J. HIBSHER (John D. Kircher, Adam J. Rosen, *of counsel*), Bryan Cave LLP, New York, NY.

Appeal from the United States District Court for the Southern District of New York (Kaplan, *J.*).

ON CONSIDERATION WHEREOF, it is hereby **ORDERED, ADJUDGED**, and **DECREED** that the judgment of the district court dated January 29, 2007, be and hereby is **AFFIRMED**.

Plaintiffs-Appellants Alliance Security Products, Inc., and Alliance Security International, LLC (collectively "Alliance") appeal from a judgment of the district court entered January 29, 2007, granting defendant-appellee Fleming & Company's motion for summary judgment dismissing the complaint, and denying plaintiffs' motion for a preliminary injunction. We assume the parties' familiarity with the facts, procedural history, and specification of issues on appeal.

By way of background, the chemical compound potassium-iodide blocks the uptake of radioactive iodine by the thyroid gland, making it beneficial for people exposed to radiation, say after a nuclear disaster. In 2003, Alliance came to Fleming, which already manufactured and sold a raspberry-flavored potassium-iodide syrup called "PIMA" as a cough expectorant, and revealed its marketing plan to sell a liquid potassium-iodide solution in a palatable base, equipped with a dropper and a child-safe cap, in communities potentially under threat of a nuclear

disaster due to terrorist attack. Although initially promising, negotiations between the parties soon broke down. Shortly thereafter, PIMA syrup was approved by the Food & Drug Administration ("FDA") for use as a radiation protectant, re-branded as "ThyroShield," and Fleming signed a contract to sell millions of bottles to the Department of Health and Human Services. Alliance brought this diversity action alleging under various contract- and tort-based theories of New York law that Fleming misappropriated Alliance's idea.

We review a district court's grant of summary judgment *de novo*. *NextG Networks of NY, Inc. v. City of New York*, 513 F.3d 49, 52 (2d Cir. 2008). In essence, however, we affirm for substantially the reasons stated by the district court in its comprehensive memorandum opinion, dated January 26, 2007. *See Alliance Sec. Prods., Inc. v. Fleming Co.*, 471 F. Supp. 2d 452 (S.D.N.Y. 2007). As the district court noted, none of Alliance's ideas, considered separately or in the aggregate, are sufficiently novel to warrant protection under New York law. *See Murray v. Nat'l Broad. Co.*, 844 F.2d 988, 993-94 (2d Cir. 1988) (holding that "New York law requires that an idea be original or novel in order for it to be protected as property") (abrogated on other grounds by *Nadel v. Play-by-Play Toys & Novelties, Inc.*, 208 F.3d 368, 376 (2d Cir. 2000)). Alliance is correct in noting that we have held that under a tort-based misappropriation theory a plaintiff must prove novelty with respect to the world at large, but under a contract-based theory a plaintiff need only prove novelty to the defendant. *Nadel*, 208 F.3d at 376; *see also Apfel v. Prudential-Bache Sec. Inc.*, 81 N.Y.2d 470, 477, 616 N.E.2d 1095, 600 N.Y.S.2d 433 (1993). In this case, however, as

the district court found, Alliance's ideas were not novel either to the defendants or the rest of the world. When "an idea consists in essence of nothing more than a variation on a basic theme . . . novelty cannot be found to exist." *Murray*, 844 F.2d at 993. *See also Downey v. Gen. Foods Corp.*, 31 N.Y.2d 56, 61-62, 286 N.E.2d 257, 334 N.Y.S.2d 874 (1972). Here, Fleming had manufactured a liquid potassium-iodide with a raspberry flavor since 1968. Although Fleming marketed its syrup primarily as a cough expectorant in hospitals, potassium-iodide's effectiveness as a radiation protectant was general knowledge and was trumpeted by the FDA after the terrorist attacks of September 11, 2001. Furthermore, the record demonstrates that Fleming knew PIMA syrup could be used in this way by patients of all ages, as evidenced by the facts that it sent some of the product to assist victims of the Chernobyl disaster, that it contacted the Nuclear Regulatory Commission ("NRC") in 1998 about stockpiling the syrup in case of a nuclear disaster, and that it attempted to provide the syrup to the Commonwealth of Pennsylvania for the same purpose. Furthermore, Fleming had already hit on the idea of marketing the drug to children, as its letters to both the NRC and Pennsylvania suggested that PIMA syrup is appropriate for all ages. Any notion that Alliance came up with the proper dosage for children is belied by the FDA's 2001 guidance, which spelled that out explicitly for potassium-iodide tablets, and the 2002 Physicians' Desk Reference, which did so for PIMA syrup specifically. The notion of obtaining FDA approval for the drug for a new use had also occurred to Fleming, as it had been in correspondence with the FDA about just that prior to

meeting with Alliance. And that is essentially the sum total of what Alliance claims to have brought to the table in the parties' 2003 meeting.

It is true that Fleming's prior efforts had been sporadic and ultimately unsuccessful, and it is likely that it was the meeting with Alliance that opened Fleming's eyes to the possibilities of the strategy it had put on hold. But even if Alliance clued Fleming into the concept's profitability, that fact does not render the ideas themselves novel either to Fleming or the general public; rather, they constitute only a non-protected "clever or useful adaptation of existing knowledge." *Educ. Sales Programs, Inc. v. Dreyfus Corp.*, 65 Misc. 2d 412, 317 N.Y.S.2d 840, 844 (Sup. Ct. 1970); *see also Murray*, 844 F.2d at 993 ("where, as here, an idea consists in essence of nothing more than a variation on a basic theme . . . novelty cannot be found to exist"). As such, summary judgment is appropriate. *Ferber v. Sterndent Corp.*, 51 N.Y.2d 782, 783-784, 412 N.E.2d 1311, 433 N.Y.S.2d 85 (1980) ("In order to successfully oppose a motion for summary judgment, plaintiff must come forward with some admissible proof that would require a trial of the material questions of fact on which his claim rests. Absent a showing of novelty, plaintiff's action to recover damages for illegal use of 'confidentially disclosed ideas' must fail as a matter of law.").

We have considered Alliance's remaining claims and consider them to be without merit. For the foregoing reasons, the judgment of the district court is hereby **AFFIRMED**.

FOR THE COURT:
CATHERINE O'HAGAN WOLFE, CLERK

By: /s/ Franklin Perez

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ALLIANCE SECURITY PRODUCTS, INC., et al.,

Plaintiffs,

-against-

05 Civ. 5214 (LAK)

FLEMING COMPANY,

Defendant.

MEMORANDUM OPINION

Appearances:

Frank H. Penski
Erika J. Duthiers
Tamar Duvdevani
NIXON PEABODY, LLP
Attorneys for Plaintiffs

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LEWIS A. KAPLAN, *District Judge.*

Plaintiffs Alliance Security Products, Inc. ("ASP") and Alliance Security International, LLC ("ASI") allege that defendant Fleming and Company, Pharmaceuticals ("Fleming"), misappropriated their idea to manufacture and market a potassium iodide liquid solution to prevent thyroid cancer in children exposed to radiation. Plaintiffs seek to

enjoin Fleming from selling a product called ThyroShield, which they claim is their product marketed according to their unique business plan. Fleming moves for summary judgment dismissing the complaint. Plaintiffs move for a preliminary injunction.

Facts

I. Rule 56.1 Statements

A preliminary matter must be addressed before getting to the pertinent facts.

On a motion for summary judgment, the moving party bears the burden of demonstrating that there is no genuine issue of material fact and that it is entitled to judgment as a matter of law. In considering such a motion, all facts and inferences reasonably drawn therefrom are construed in favor of the nonmoving party.[1]

In addition, Local Civil Rule 56.1 of this Court provides that a party moving for summary judgment must file a concise statement of material facts it claims are undisputed, with each statement of fact followed by a citation to admissible evidence. Each statement then is deemed undisputed for purposes of the summary judgment motion unless the nonmovant specifically denies it, citing to competent evidence.[2]

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[1] *E.g., Nationwide Life Ins. Co. v. Bankers Leasing Ass'n, Inc.*, 182 F.3d 157, 160 (2d Cir. 1999).

[2] S.D.N.Y. CIV. R. 56.1.

Plaintiffs have failed properly to put many of defendant's statements of fact into dispute. First, they respond to several of defendant's statements without references to admissible evidence.[3] Statements responded to in this way are deemed undisputed for purposes of this motion.[4]

Second, plaintiffs respond to a number of defendant's statements by stating that they "lack[ ] knowledge or information sufficient to form a belief as to whether" the statements are true.[5] Such responses are insufficient to put a statement of fact into dispute. Statements responded to in this way are deemed undisputed as well.[6]

Finally, plaintiffs respond to many of defendant's statements by making legal arguments. For example, in paragraph 14, plaintiffs concede that it has been common knowledge for decades that ingesting potassium iodide is a safe way of aiding the prevention of thyroid cancer, but go on to "dispute[ ] any implication that this fact renders Alliance's confidential information and novel idea 'common knowledge.'"[7] Such legal arguments, which are plentiful in plaintiff's counter-statement, belong in

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[3] *See, e.g.*, Pl. Rule 56.1 St. ¶112.

[4] *See Archie Comic Publ'ns, Inc. v. DeCarlo*, 258 F. Supp. 2d 315, 317-19 (S.D.N.Y. 2003), *aff'd*, 88 Fed. Appx. 468 (2d Cir. March 3, 2004), *cert. denied*, 543 U.S. 813, 125 S. Ct. 50 160 L. Ed. 2d 18 (2004).

[5] *E.g.*, Pl. Rule 56.1 St. ¶¶3, 27, 40.

[6] *See Archie Comic Publ'ns*, 258 F. Supp. 2d at 317-19.

[7] Pl. Rule 56.1 St. ¶14.

briefs, not *Rule 56.1* statements, and so are disregarded in determining whether there are genuine issues of material fact.[8]

II. Undisputed Facts

In light of the foregoing, the following facts are undisputed for purposes of this motion unless otherwise noted.

A. Potassium Iodide

It has been well known, at least since the late 1970s, that ingesting potassium iodide ("KI") is a safe and effective way to block the uptake of radioactive iodine by the thyroid gland. It therefore aids in preventing the development of thyroid cancer in those exposed to radiation.[9]

1. PIMA

Defendant develops, manufactures, and sells ethical pharmaceutical and over-the-counter products.[10] Beginning in 1968, it manufactured a raspberry flavored syrup called PIMA,[11] which

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[8] *See Archie Comic Publ'ns*, 258 F. Supp. 2d at 318 & n.9 (counter-statement including legal conclusions without material facts to support them is insufficient to put facts into dispute); *see also Jessamy v. City of New Rochelle*, 292 F. Supp. 2d 498, 509 n.12 (S.D.N.Y. 2003) (no heed given to legal conclusions in Rule 56.1 statement).

[9] Def. Rule 56.1 St. ¶14 & Exs. 10 (Foltin Dep. 81-84), 13 (FDA guidance document) (recounting previous FDA findings dating from 1978 about KI and thyroid cancer prevention).

[10] Def. Rule 56.1 St. ¶1.

[11] *Id.* ¶¶1, 12.

originally was marketed as a cough expectorant,[12] but was known to have additional valuable properties because it contained KI.[13]

In 1986, Fleming supplied PIMA to the victims of the Chernobyl disaster to be used as a thyroid protectant.[14] In 1998, Fleming contacted the Nuclear Regulatory Commission ("NRC"), which had

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[12] *Id.* ¶12 (citing Cpt. ¶3); Baker Decl. ¶¶5, 42; Duthiers Decl. Ex. A (Johnson Dep. 132).

[13] Def. Rule 56.1 St. ¶¶12, 14.

[14] Plaintiffs appear to dispute the fact that Fleming supplied PIMA to Chernobyl victims in their Rule 56.1 statement. Pl. Rule 56.1 St. ¶16. However, plaintiffs conceded the fact in their pleadings, Cpt. ¶77 n.2 ("Fleming delivered some PIMA syrup to address the radiation concerns of someone in the Eastern European bloc after the Chernobyl nuclear accident in 1986."), and the co-owner and chief executive officer of ASI and ASP, Steven Baker, referenced this fact in a slide show presentation he gave to Fleming in 2003. *See* Def. Rule 56.1 St. Ex. 15 (slide show).

Plaintiffs claim also that Fleming has failed to point to competent evidence to support this fact. Pl. Rule 56.1 St. ¶16. However, Ted Feller, a long time Fleming employee, stated in his affidavit that Fleming supplied thousands of bottles of PIMA to Chernobyl victims in 1986 and that he "was directly involved in facilitating the shipment of PIMA in response to the Chernobyl disaster." Def. Rule 56.1 St. Ex. 7 (Feller Decl. ¶4).

Finally, plaintiffs point to the fact that the evidence conflicts as to exactly how many bottles of PIMA Fleming supplied to the Chernobyl victims, *see id.* Exs. 12 (letter from Fleming to FDA, dated Oct. 24, 2003) (5,000 pints), 14 (letter from Fleming to Nuclear Regulatory Commission) (20,000 bottles), 16 ("Cracker Barrel Sessions" letter) (10,000 pints), and fails to establish that PIMA ever was used by Chernobyl victims. This misses the point. The relevant fact is that Fleming supplied *some* PIMA to Chernobyl victims because it knew of the beneficial effects of KI, regardless of how much it sent or whether it ever was used.

recommended creating national stockpiles of KI to improve government preparedness for nuclear disasters,[15] and asked to be considered as a provider of KI for these stockpiles.[16] At least as early as 1999, Fleming included in its PIMA product insert a paragraph indicating that the syrup could be used as a radiation protectant for the thyroid gland.[17]

2. Public Awareness

Federal agencies have been advocating the stockpiling of KI products near nuclear power plants since the 1980s.[18] Public awareness of the potential need for KI grew after the September 11, 2001 terrorist attack. Numerous politicians and news commentators began discussing the possibility of terrorist attacks on U.S. nuclear facilities and the need to be prepared for the medical emergencies that could follow. Several commentators mentioned specifically the need to stockpile KI.[19]

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[15] Def. Rule 56.1 St. ¶22 & Ex. 21 (NRC draft report, dated July 1998).

[16] *Id.* ¶24 & Ex. 14 (letter to NRC chairman, dated Sept. 2, 1998).

[17] Def. Rule 56.1 St. ¶26 (citing Cpt. ¶77 n.2) & Ex. 24 (product insert).

[18] Def. Rule 56.1 St. Ex. 56 (Federal Emergency Management Agency notice, dated July 24, 1985); *Id.* ¶22 & Ex. 21 (NRC draft report, dated July 1998).

[19] *E.g.*, Def. Rule 56.1 St. ¶¶41, 42, 44, 47, 48-49, 56-57 & Exs. 33 (*Boston Globe* article recommending KI pill stockpiles), 34 (CNN article discussing NRC's concern about attacks on nuclear plants), 36 (*Seattle Post-Intelligencer* article discussing the Department of Health and Human Services' decisions to buy millions of doses of KI for radiation emergencies), 39 (Senate testimony of Dr. Irwin Redlener, president of Children's

In late 2001, presumably in response to this heightened awareness, the FDA published a guidance document in which it outlined procedures for administering KI to children in the event of a radiation emergency. The document listed safe dose sizes for children of various ages and recommended dissolving solid tablets in liquid to ease ingestion, especially when administering KI to babies.[20]

3. Fleming Contacts the NRC

In early 2002, Fleming offered again to provide the NRC with PIMA for government stockpiles of KI.[21] It was told, however, that the NRC had awarded a two-year contract for KI pills to a company called Anbex, in part because the NRC's "bid specs required that the manufacturer have FDA approval for their drug product,"[22] which Fleming lacked for PIMA. At that time, PIMA was available only by prescription and was not FDA-approved for use as a radiation protectant. Nor had it been sold with pediatric droppers or child-safe caps.[23]

Health Fund, regarding the threat of terrorist attacks on nuclear facilities and the need to stockpile KI), 43 (American Thyroid Association 2002 recommendation for stockpiling KI at facilities "such as schools, hospitals, clinics, post offices, and police and fire stations"), 51 (*Newsday* article advocating stockpiling KI in households, schools, and daycare centers).

[20] *Id.* ¶¶35-38 & Ex. 13 (FDA guidance document, dated Dec. 2001).

[21] *Id.* ¶45 & Ex. 38 (letter from NRC representative with prior correspondence, dated Feb. 15, 2002, included).

[22] *Id.* ¶46 & Ex. 38 (letter to Tom Johnson dated Feb. 25, 2002).

[23] *See id.* ¶51 & Ex. 5 (Johnson Decl. ¶¶11-14); Duthiers Decl Ex. A (Johnson Dep. 86-89); Baker Decl. ¶56.

B. The Parties Meet

Plaintiffs sell safety and antiterrorism equipment. According to plaintiffs, while public awareness of the potential need for KI was growing, Steven Baker, co-owner and chief executive officer of both ASP and ASI, recognized that there was a market for a child-friendly KI solution that could be used in the event of a nuclear emergency. His research into existing manufacturers of KI products led him to Fleming.[24]

1. The Nondisclosure Agreement

Baker approached Fleming in April 2003, and the parties met to discuss the possibility of marketing PIMA, or some similar solution, as a child-friendly KI liquid product to be used in the event of a radiological disaster.[25]

The parties met to discuss this possibility in more depth in May 2003, at which time ASI and Fleming entered into a written nondisclosure agreement that prohibited the disclosure to third parties of any

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[24] Baker Decl. ¶¶3-5.

[25] Def. Rule 56.1 St. ¶63; Cpt. ¶52. The parties dispute whether they discussed adapting the existing PIMA formula to new uses or inventing a new formula altogether. That is, plaintiffs claim that the parties met to discuss "new product uses of the chemicals in PIMA," Pl. Rule 56.1 St. ¶63, rather than "using Fleming's existing liquid KI product" in terrorism survival kits as defendant avers, Def. Rule 56.1 St. ¶63. Regardless, ThyroShield, the product Fleming now produces and that plaintiffs claim is their misappropriated idea, is the PIMA formula with a new name. *See id.* ¶126. To the extent plaintiffs' allegedly novel idea was to create a new KI formula, it was not misappropriated. Whether the possibility of developing a new formula was discussed is not an issue.

confidential information the parties would share.[26] The agreement expressly excluded protection for information that was (1) available to the public at the date of the disclosure, or thereafter became generally and conveniently available to the public through no breach of the agreement, (2) both known to the receiver prior to the time of disclosure, as evidenced by contemporaneous dated written records, and not acquired from the discloser, or (3) received by independent sources that had the right to disclose the information, without such information having been solicited or obtained by using confidential information protected by the agreement.[27]

2. The Slide Show

The parties met again on July 18, 2003. Baker made a slide presentation revealing plaintiffs' product idea and business plan.[28] According to the complaint, the "new" product concept was a liquid KI solution in a palatable base sold with graduated pediatric droppers and child-safe caps. The product

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[26] Def. Rule 56.1 St. ¶71. The parties quibble over whether ASP also was a party to the nondisclosure agreement and whether any of the information subsequently disclosed to Fleming came from ASI or ASP. As will become clear, the difference is immaterial. Even if, as plaintiffs claim, both ASI and ASP were parties to the contract, there was no breach because none of the information allegedly misappropriated by Fleming was protected under the agreement.

[27] *Id.* Ex. 48 (nondisclosure agreement ¶2).

[28] *Id.* ¶79 & Ex. 15 (slide show); Cpt. ¶¶62, 64.

would be approved by the FDA for over-the-counter sales and used in emergency response to nuclear disasters.[29]

The business plan consisted of information about the risks of terrorist attacks on nuclear power plants in the United States, the superiority of the "new" product concept over existing KI products, and strategies for obtaining FDA approval, marketing and distributing the product, and raising public awareness about the need for KI.[30]

3. The Negotiations

The parties began negotiating an arrangement whereby Fleming would manufacture a KI product for plaintiffs, who would purchase and market the product.[31] Negotiations soured, however, and Baker began discussions with another pharmaceutical company, Taro Pharmaceutical Industries, Ltd. ("Taro").[32]

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[29] Cpt. ¶2.

[30] *See* Def. Rule 56.1 St. ¶108; Cpt. ¶68.

[31] Def. Rule 56.1 St. ¶98; Cpt. ¶78. The parties dispute how extensive their negotiations after the July 2003 slide show were. *See* Pl. Rule 56.1 St. ¶98. The dispute is immaterial. As plaintiffs do not appear to allege that confidential information was exchanged after the slide show, how long or extensively the parties communicated thereafter does not bear on the issue of whether Fleming misappropriated a novel idea belonging to plaintiffs.

[32] Baker Decl. ¶¶130, 134-36.

C. Development of ThyroShield

1. Orphan Drug Status

The Orphan Drug Act ("ODA"),[33] provides incentives to develop and market drugs for rare diseases, or "orphan drugs." A "rare disease" is one that either affects fewer than 200,000 people in the United States, or "for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug."[34] Once the FDA approves a drug designated as an orphan drug, it may not approve another drug for treatment of the same disease for a period of seven years.[35]

On June 8, 2004, after the NRC-Anbex contract expired, Fleming applied to the Office of Orphan Products Development for orphan drug designation of its KI product for use as a pediatric thyroid protectant in the event of a radiation emergency. The application was granted on November 17, 2004.[36]

When they learned about Fleming's application for orphan drug status, plaintiffs and Taro stopped negotiations. According to plaintiffs, this

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[33] 21 U.S.C. § 360aa *et seq.*

[34] *Id.* § 360bb.

[35] *Id.* § 360cc.

[36] Def. Rule 56.1 St. ¶¶120, 123 & Exs. 3 (Love Decl. ¶17), 63 (letter from FDA, dated Nov. 17, 2004); Cpt. ¶94.

was because orphan drug status would prevent manufacturers other than Fleming from entering the U.S. market for oral KI solutions.[37]

2. FDA Approval

Fleming filed on July 23, 2004 for FDA approval of a liquid KI solution, which it originally named Famli-GUARD, for use as a thyroid blocking agent in nuclear emergencies.[38] Fleming then changed the name of its product to ThyroShield in order to make it more consistent with previously approved KI product names.[39] On January 12, 2005, the FDA approved Fleming's product,[40] which was the PIMA formula, packaged in the same bottle size that Fleming had been using for many years, without a child-safe cap.[41]

3. Government Contract

On March 18, 2005, the Department of Health and Human Services ("HHS") awarded a $5.7 million contract to Fleming for the manufacture and delivery of 1.7 million bottles of ThyroShield. The contract did

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[37] Baker Decl. ¶¶137-39.

[38] Def. Rule 56.1 St. ¶121 & Ex. 61 (letter to FDA, dated July 23, 2004).

[39] *Id.* ¶122 & Exs. 3 (Love Decl. ¶16), 62 (letter to FDA, dated Nov. 29, 2004).

[40] *Id.* ¶125 & Exs. 6 (Patullo Decl. ¶10), 65 (letter from FDA, dated Jan. 12, 2005); Cpt. ¶96.

[41] *Id.* ¶126-27 & Ex. 6 (Patullo Decl. ¶11-12).

not require the bottles to have child-safe caps and permitted the government to place additional orders at later dates.[42]

In late 2005, HHS asked Fleming to retrofit the 1.7 million bottles with child-safe caps and to include this feature in future orders as well. Fleming agreed to incorporate the caps and the government ordered an additional 3.1 million bottles.[43]

III. This Action

The thrust of the complaint is that Baker revealed confidential business strategies that Fleming misappropriated to create and market ThyroShield. The complaint sounds in misappropriation of ideas, unfair competition, accounting, conversion, unjust enrichment, and misappropriation of trade secrets. It alleges also breach of the written nondisclosure agreement.

Discussion

Summary judgment is appropriate if there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law.[44] Where the burden of proof at trial would fall on the nonmoving party, it ordinarily is sufficient for the movant to point to a lack of evidence to go to the trier of fact on an essential element of the nonmovant's

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[42] *Id.* ¶¶128-29 & Ex. 66 (HHS contract and order form).

[43] *Id.* ¶¶129-130 & Exs. 3 (Love Decl. ¶¶18-19), 31 (HHS contract and order modification).

[44] *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986); *White v. ABCO Eng'g Corp.*, 221 F.3d 293, 300 (2d Cir. 2000); *see also* FED. R. CIV. P. 56(c).

claim.[45] In that event, the nonmoving party must come forward with admissible evidence sufficient to raise a genuine issue of fact for trial in order to avoid summary judgment.[46]

I. Novelty

Under New York law, "lack of novelty in an idea is fatal to *any* cause of action for its unauthorized use."[47] Moreover, the nondisclosure agreement in this case expressly excluded protection for information already publicly available or known to the recipient. The issue of novelty therefore is central to this case.

To establish novelty, a plaintiff's idea need not reflect a flash of genius, but must show genuine invention and not merely a clever or useful adaptation of existing knowledge.[48] An idea that combines several known ideas may be novel, but it is not novel if it "consists of nothing more than a variation on a basic theme."[49] That is, there is a

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[45] *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986); *Virgin Atl. Airways Ltd. v. British Airways PLC*, 257 F.3d 256, 273 (2d Cir. 2001).

[46] *See, e.g., Nora Beverages, Inc. v. Perrier Group of Am., Inc.*, 269 F.3d 114, 123-24 (2d Cir. 2001); *Raskin v. Wyatt Co.*, 125 F.3d 55, 65-66 (2d Cir. 1997).

[47] *Kavanau v. Courtroom Television Network*, No. 91 Civ. 7959 (RPP), 1992 U.S. Dist. LEXIS 11472, 1992 WL 197430 * 4 (S.D.N.Y. Aug. 3, 1992) (emphasis in original) (quoting *Downey v. Gen. Foods Corp.*, 31 N.Y.2d 56, 61, 286 N.E.2d 257, 259, 334 N.Y.S.2d 874 (1972)).

[48] *AEB & Assocs. Design Group, Inc. v. Tonka Corp.*, 853 F. Supp. 724, 734 (S.D.N.Y. 1994) (internal citations and quotations omitted).

[49] *Id.*

distinction between "novelty of an idea," which is protectible, and "novelty of its execution," which is not.[50] The latter is "only the judicious use of existing means, or the mixture of known ingredients in somewhat different [proportions]."[51] It is not protected because it "partake[s] more of the nature of elaboration and renovation than innovation."[52]

Fleming argues that plaintiffs' claims fail because each element of their proposed product and marketing ideas was not novel.

II. Product Concept

The alleged "new" product concept was (1) a liquid KI solution (2) in a palatable base (3) with a graduated pediatric dropper and child-safe cap, (4) to be approved by the FDA for over-the-counter sale and use in emergency response to nuclear disasters.

A. Liquid Solution with Palatable Base

The idea of a palatable KI liquid product had been well known to Fleming for decades. It had manufactured and sold PIMA, a KI liquid product with a raspberry flavor, since 1968.

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[50] *Victor G. Reiling Assocs. v. Fisher-Price, Inc.*, 450 F. Supp. 2d 175, 180 (D. Conn. 2006) (applying New York law and quoting Kavanau, 1992 U.S. Dist. LEXIS 11472, 1992 WL 197430 at * 6).

[51] *Id.*

[52] *Id.*

B. Child-safe Caps and Graduated Droppers

The idea to use child-safe caps and graduated droppers was not novel either. It is common practice in the pharmaceutical industry to sell products with these features.[53] Moreover, the proper dose of KI for children was public knowledge at least as early as 2001 when the FDA published its guidance document, which discussed the advantages of using KI in nuclear emergencies and recommended dosages.

C. FDA Approval and Emergency Use

Finally, Fleming knew that PIMA was effective for combating thyroid cancer. It supplied PIMA to victims of the Chernobyl disaster and included information about radiation treatment in its product inserts as early as 1999. Moreover, Fleming knew, as demonstrated by its correspondence with the NRC, that its product easily was administrable to children, that KI might be stockpiled around nuclear power plants, and that FDA approval was required at least to get a contract with the NRC to supply KI for government stockpiles.

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[53] *See* Def Rule 56.1 St. ¶¶105, 107 & Ex 10 (Foltin Dep. 89-93, 118-19). Even if the idea of child-safe caps were novel, Fleming did not misappropriate it from plaintiffs. ThyroShield, as approved by the FDA and originally supplied to HHS, did not include the child-safe caps. It was not until HHS requested the retrofitting of the first 1.7 million bottles and the inclusion of child-safe caps in all future orders that Fleming included them.

III. Business Plan

Plaintiffs' allegedly novel business plan consisted of (1) information about the potential risk of a terrorist attack on a nuclear power plant in the United States, (2) the need to stockpile liquid KI for counteracting the effects of radiation, (3) the increased market due to the possibility of a terrorist attack, (4) the ease of administering liquid KI solutions, as opposed to solid pills, to children, (5) the need to obtain FDA approval for an over-the-counter liquid KI solution, (6) a strategy for obtaining such approval, (7) a strategy for marketing the liquid KI solution to governments, schools, drug stores, and child care centers, (8) a strategy for distributing the liquid KI product, and (9) a strategy for educating the public about the need for liquid KI.[54]

A. Need for Liquid KI Products

Plaintiffs have failed to establish that the information Baker disclosed with respect to the first five elements was novel.

The information about nuclear power plants that plaintiffs disclosed at the slide show consisted of three publicly available maps showing the locations of power plants in the United States.[55]

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[54] *Id.* ¶108; Cpt. ¶68.

[55] Def. Rule 56.1 ¶95 & St. Ex. 15 (slide show). Plaintiffs claim that these maps were used simply as a springboard for Baker's much more detailed discussion of nuclear power plants in the United States. Pl. Rule 56.1 St. ¶95. Baker stated in his declaration that he informed "Fleming about the new reality of terrorism in the United States and the security measures the United States was implementing to protect citizens from terrorist attacks," including passing Project Bioshield, "a $5.6

Second, the need to stockpile KI products near nuclear power plant sites already was known to Fleming, as demonstrated by its offers to the NRC in 1998 and 2002 to be considered as a supplier of KI for government stockpiles.

Third, the increased market due to rising concerns about terrorist attacks was public knowledge. After September 11, 2001, numerous politicians and news commentators called on the U.S. government to improve preparedness for nuclear disasters and stockpile KI.

Fourth, the FDA had announced publicly the superiority of liquid-form KI in its guidance document outlining procedures for administering KI to children. In that document the FDA specifically recommended dissolving KI pills in liquid.

And fifth, the need to obtain FDA approval, at least to get a contract with the NRC, already was known to Fleming from its 2002 correspondence with the NRC, in which it was told Anbex's KI product had been selected for government stockpiles because it had FDA approval.

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billion fund intended to encourage the development of drugs, vaccines and other defenses against [terrorist] attacks." Baker Decl. ¶102. This does not establish, however, that Baker's information was novel, or that Fleming used it to develop ThyroShield. Information about the laws Congress passes of course is public, and Baker admitted in his deposition that he did not consider the information about Project Bioshield to be confidential, Def. Rule 56.1 St. Ex. 8 (Baker Dep. 70). Moreover, Fleming offered years earlier to produce PIMA for government stockpiles of KI near nuclear power plants, thus showing that it knew of the "security measures the United States was implementing to protect its citizens."

B. Marketing Strategies

Plaintiffs have failed to produce evidence showing that the remaining elements of their business plan, their marketing and regulatory strategies, were more intricate or original than the basic, common sense steps any seller would take to market a drug, or steps that already had been recommended publicly for the distribution of KI products.

The idea of providing governments, schools, drug stores, and child care centers with KI products was touted publicly after the events of September 11, 2001. It was not novel.

The evidence shows that plaintiffs' strategy for obtaining FDA approval involved only calling the FDA and asking it for guidance about how to proceed,[56] that their distribution strategy consisted of gaining exclusive rights to a product and then distributing it to major drug stores like CVS,[57] and that their strategy for alerting the public was to "create awareness" and "contact key players."[58] These strategies are too obvious to be called novel.[59]

Plaintiffs deny that their regulatory and marketing strategies were this simple, and assert that Baker revealed much more detailed plans

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[56] *Id.* ¶112 & Ex. 9 (Fenton Dep. 182-83).

[57] *Id.* ¶96 & Ex. 15 (slide show).

[58] *Id.* ¶93 & Ex. 15 (slide show).

[59] Indeed, Fleming already had employed the distribution strategy of selling products to major drug store chains like CVS. *Id.* ¶60 & Ex. 5 (Johnson Decl. ¶4).

during the slide show presentation.[60] They fail, however, to point to admissible evidence to support these assertions.[61]

C. Additional Information

Plaintiffs contend that the slides alone do not reveal all of the information Baker disclosed. To support this, they offer Baker's preparatory notes for the July 18, 2003 slide show and his notes memorializing his meeting the night before with Ted Feller, a Fleming representative.[62]

To the extent the notes are decipherable, nothing in them aids plaintiffs' case. The notes, along with Baker's deposition testimony, show only that Baker conducted extensive market research, interviewed customers, and confirmed that there was public desire for a child-friendly liquid KI product. While he revealed certain pieces of information to Fleming that may have been confidential, such as names of high-profile customers Baker interviewed, research methods, names of the members of Baker's research team, and one brand name Baker considered for his product,[63] the evidence does not show that Fleming relied in any way on this information in deciding to sell its existing KI product to the government, which it had been trying to do at least since 2002.

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[60] Pl. Rule 56.1 St. ¶¶96, 112.

[61] *See id.*

[62] *See* Baker Decl. Ex. 25.

[63] *See* Def. Rule 56.1 St. Ex. 8 (Baker Dep. 117-129, 160-61, 168, 169).

IV. Combination of Non-novel Ideas

Plaintiffs argue that even if the constituent elements of its product concept and business plan were not novel, the entire package, taken as whole, was original. This is demonstrated, they claim, by the fact no product like ThyroShield existed when the parties first met.

This argument is unconvincing. The need for KI liquid solution was well known in 2003. Fleming had been making just such a product for over thirty years and had labeled it as a radiation protectant at least since 1999. ThyroShield simply was PIMA in a new bottle and marketed with a different purpose. It was a not a novel product, but rather a useful adaptation of an existing one. In other words, it partook "more of the nature of elaboration and renovation than innovation."[64]

This is not to say that Fleming necessarily received no benefit from meeting with plaintiffs. Perhaps it gained from learning that Baker's research confirmed the existence of a liquid KI market. And it likely benefited from learning that other companies were moving to tap that market. This, however, does not create any issue for trial. Fleming was prohibited from misappropriating novel ideas, not from being spurred to develop a product it long had contemplated making.

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[64] *Victor G. Reiling Assocs.*, 450 F. Supp. 2d at 180.

Conclusion

Defendant's motion for summary judgment dismissing the complaint is granted. Plaintiffs' motion for a preliminary injunction is denied.

SO ORDERED.

Dated: January 26, 2007

/s/ Lewis A. Kaplan
Lewis A. Kaplan
United States District Judge

The Orphan Drug Act (as amended)

CONGRESSIONAL FINDINGS FOR THE ORPHAN DRUG ACT

The Congress finds that---

(1) there are many diseases and conditions, such as Huntington's disease, myoclonus, ALS (Lou Gehrig's disease), Tourette syndrome, and muscular dystrophy which affect such small numbers of individuals residing in the United States that the diseases and conditions are considered rare in the United States;

(2) adequate drugs for many of such diseases and conditions have not been developed;

(3) drugs for these diseases and conditions are commonly referred to as "orphan drugs";

(4) because so few individuals are affected by any one rare disease or condition, a pharmaceutical company which develops an orphan drug may reasonably expect the drug to generate relatively small sales in comparison to the cost of developing the drug and consequently to incur a financial loss;

(5) there is reason to believe that some promising orphan drugs will not be developed unless changes are made in the applicable Federal laws to reduce the costs of developing such drugs and to provide financial incentives to develop such drugs; and

(6) it is in the public interest to provide such changes and incentives for the development of orphan drugs.

RECOMMENDATIONS FOR INVESTIGATIONS OF DRUGS FOR RARE DISEASES OR CONDITIONS

SEC. 525 [360aa].

(a) The sponsor of a drug for a disease or condition which is rare in the States may request the Secretary to provide written recommendations for the nonclinical and clinical investigations which must be conducted with the drug before---

(1) it may be approved for such disease or condition under section 505,

(2) if the drug is an antibiotic, it may be certified for such disease or condition under section 507, or

(3) if the drug is a biological product, it may be licensed for such disease or condition under section 351 of the Public Health Service Act. If the Secretary has reason to believe that a drug for which a request is made under this section is a drug for a disease or condition which is rare in the States, the Secretary shall provide the person making the request written recommendations for the nonclinical and clinical investigations which the Secretary believes, on the basis of information available to the Secretary at the time of the request under this section, would be necessary for approval of such drug for such disease or condition under section 505, certification of such drug for such disease or condition under section 507, or licensing of such drug for such disease or condition under section 351 of the Public Health Service Act.

The Secretary shall by regulation promulgate procedures for the implementation of subsection (a).

DESIGNATION OF DRUGS FOR RARE DISEASES OR CONDITIONS

SEC. 526 [360bb]. (a)(1) The manufacturer or the sponsor of a drug may request the Secretary to designate the drug as a drug for a rare disease or condition. A request for designation of a drug shall be made before the submission of an application under section 505(b) for the drug, the submission of an application for certification of the drug under section 507, or the submission of an application for licensing of the drug under section 351 of the Public Health Service Act. If the Secretary finds that a drug for which a request is submitted under this subsection is being or will be investigated for a rare disease or condition and---

(A) if an application for such drug is approved under section 505,

(B) if a certification for such drug is issued under section 507, or

(C) if a license for such drug is issued under section 351 of the Public Health Service Act, the approval, certification, or license would be for use for such disease or condition, the Secretary shall designate the drug as a drug for such disease or condition. A request for a designation of a drug under this subsection shall contain the consent of the applicant to notice being given by the Secretary under subsection (b) respecting the designation of the drug.

(2) For purposes of paragraph (1), the term "rare disease or condition" means any disease or condition which (A) affects less than 200,000 persons in the United States, or (B) affects more than 200,000 in

the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will recovered from sales in the United States of such drug. Determinations under the preceding sentence with respect to any drug shall be made on the basis of the facts and circumstances as of the date the request for designation of the drug under this subsection is made.

(b) A designation of a drug under subsection (a) shall be subject to the condition that---

(1) if an application was approved for the drug under section 505(b), a certificate was issued for the drug under section 507, or a license was issued for the drug under section 351 of the Public Health Service Act, the manufacturer of the drug will notify the Secretary of any discontinuance of the production of the drug at least one year before discontinuance, and

(2) if an application has not been approved for the drug under section 505(b), a certificate has not been issued for the drug under section 507, or a license has not been issued for the drug under section 351 of the Public Health Service Act and if preclinical investigations or investigations under section 505(i) are being conducted with the drug, the manufacturer or sponsor of the drug will notify the Secretary of any decision to discontinue active pursuit of approval of an application under section 505(b), approval of an application for certification under section 507, or approval of a license under section 351 of the Public Health Service Act.

(c) Notice respecting the designation of a drug under subsection (a) shall be made available to the public.

(d) The Secretary shall by regulation promulgate procedures for the implementation of subsection (a).

PROTECTION FOR DRUGS FOR RARE DISEASES OR CONDITIONS

SEC. 527 [360cc]. (a) Except as provided in subsection (b), if the Secretary---

(1) approves an application filed pursuant to section 505(b),

(2) issues a certification under section 507, or

(3) issues a license under section 351 of the Public Health Service Act for a drug designated under section 526 for a rare disease or condition, the Secretary may not approve another application under section 505(b), issue another certification under section 507, or issue another license under section 351 of the Public Health Service Act for such drug for such disease or condition for a person who is not the holder of such approved application, of such certification, or of such license until the expiration seven years from the date of the approval of the approved application, the issuance of the certification or the issuance of the license. Section 505(c)(2) does not apply to the refusal to approve an application under the preceding sentence.

(b) If an application filed pursuant to section 505(b) is approved for a drug designated under section 526 for a rare disease or condition, if a certification is issued under section 507 for such a drug or if a

license is issued under section 351 of the Public Health Service Act for such a drug, the Secretary may, during the seven-year period beginning on the date of the application approval, of the issuance of the certification under section 507, or of the issuance of the license, approve another application under section 505(b), issue another certification under section 507, or, issue a license under section 351 of the Public Health Service Act, for such drug for such disease or condition for a person who is not the holder of such approved application, of such certification, or of such license if---

(1) the Secretary finds, after providing the holder notice and opportunity for the submission of views, that in such period the holder of the approved application, of the certification, or of the license cannot assure the availability of sufficient quantities of the drug to meet the needs of persons with the disease or condition for which the drug was designated; or

(2) such holder provides the Secretary in writing the consent of such holder for the approval of other applications, issuance of other certifications, or the issuance of other licenses before the expiration of such seven-year period.

OPEN PROTOCOLS FOR INVESTIGATIONS OF DRUGS FOR RARE DISEASES OR CONDITIONS

SEC. 528 [360dd]. If a drug is designated under section 526 as a drug for a rare disease or condition and if notice of a claimed exemption under section 505(i) or regulations issued thereunder is filed for such drug, the Secretary shall encourage the sponsor of such drug to design protocols for clinical

investigations of the drug which may be conducted under the exemption to permit the addition to the investigations of persons with the disease or condition who need the drug to treat the disease or condition and who cannot be satisfactorily treated by available alternative drugs.

GRANTS AND CONTRACTS FOR DEVELOPMENT OF DRUGS FOR RARE DISEASES AND CONDITIONS

SEC. 5. [360ee](a) The Secretary may make grants to and enter into contracts with public and private entities and individuals to assist in (1) defraying the costs of qualified clinical testing expenses incurred in connection with the development of drugs for rare diseases and conditions, (2) defraying the costs of developing medical devices for rare diseases or conditions, and (3) defraying the costs of developing medical foods for rare diseases or conditions.

(b) For purposes of subsection (a):

(1) The term "qualified testing" means---

(A) human clinical testing---

(i) which is carried out under an exemption for a drug for a rare disease or condition under section 505(i) of the Federal Food, Drug, and Cosmetic Act (or regulations issued under such section);

(ii) which occurs after the date such drug is designated under section 526 of such Act and before the date on which an application with respect to such drug is submitted under section 506(b) or 507 of such Act or under section 351 of the Public Health Service Act; and

(B) preclinical testing involving a drug is designated under section 526 of such Act and before the date on which an application with respect to such drug is submitted under section 505(b) or 507 of such Act or under section 351 of the Public Health Service Act.

(2) The term "rare disease or condition" means

(A) in the case of a drug, any disease or conditions which (A) affects less than 200,000 persons in the United States, or (B) affects more than 200,000 in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for such disease or condition will be recovered from sales in the United States of such drug,

(B) in the case of a medical device, any disease or condition that occurs so infrequently in the United States that there is no reasonable expectation that a medical device for such disease or condition will be developed without assistance under subsection (a), and

(C) in the case of a medical food, any disease or condition that occurs so infrequently in the United States that there is no reasonable expectation that a medical food for such disease or condition will be developed without assistance under subsection (a). Determinations under the preceding sentence with respect to any drug shall be made on the basis of the facts and circumstances as of the date the request for designation of the drug under section 526 of the Federal Food, Drug, and Cosmetic Act is made.

(D) The term "medical food" means a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.

(c) For grants and contracts under subsection (a) there are authorized to be appropriated $10,000,000 for fiscal year 1988, $12,000,000 for fiscal year 1989, $14,000,000 for fiscal year 1990.

(d) STUDY. --- The Secretary of Health and Human Services shall conduct a study to determine whether the application of subchapter B of chapter V of the Federal Food, Drug, and Cosmetic Act (relating to drugs for rare diseases and conditions) and section 28 of the Internal Revenue Code of 1986 (relating to tax credit) to medical devices or medical foods for rare diseases or conditions or to both is needed to encourage the development of such devices and foods. The Secretary shall report the results of the study to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate not later than one year after the date of the enactment of this Act. For purposes of this section, the term "rare diseases or conditions" has the meaning prescribed by section 5 of the Orphan Drug Act (21 U.S.C. 360ee).

ORPHAN PRODUCTS BOARD

SEC. 227 [236]. (a) There is established in the Department of Health and Human Services a board for the development of drugs (including Biologics) and devices (including diagnostic products) for rare diseases or conditions to be known as the Orphan Products Board. The Board shall be comprised of the Assistant Secretary for Health of the Department of Health and Human Services and representatives, selected by the Secretary, of the Food and Drug Administration, the National Institutes Health, the Centers for Disease Control and, any other Federal department or agency which the Secretary determines has activities relating to drugs and devices for rare diseases or conditions. The Assistant Secretary for Health shall chair the Board.

(b) The function of the Board shall be to promote the development of drugs and devices for rare diseases or conditions and the coordination among Federal, other public, and private agencies in carrying out their respective functions relating to the development of such articles for such diseases or conditions.

(c) In the case of drugs for rare diseases or conditions the Board shall---

(1) evaluate---

(A) the effect of subchapter B of the Federal Food, Drug, and Cosmetic Act on the development of such drugs, and

(B) the implementation of such subchapter;

(2) evaluate the activities of the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration for the development of drugs for such diseases or conditions,

(3) assure appropriate coordination among the Food and Drug Administration, the National Institutes of Health, the Alcohol, Drug Abuse, and Mental Health Administration, and the Centers for Disease Control in the carrying out of their respective functions relating to the development of drugs for such diseases or conditions to assure that the activities of each agency are complementary,

(4) assure appropriate coordination among all interested Federal agencies, manufacturers, and organizations representing patients, in their activities relating to such drugs,

(5) with the consent of the sponsor of a drug for a rare disease or condition exempt under section 505(i) of the Federal Food, Drug, and Cosmetic Act or regulations issued under such section, inform physicians and the public respecting the availability of such drug for such disease or condition and inform physicians and the public respecting the availability of drugs approved under section 505(c) of such Act or licensed under section 351 of this Act for rare diseases or conditions,

(6) seek business entities and others to undertake the sponsorship of drugs for rare diseases or conditions, seek investigators to facilitate the development of such drugs, and seek business entities to participate in the distribution of such drugs, and

(7) reorganize the efforts of public and private entities and individuals in seeking the development of drugs for rare diseases or conditions and in developing such drugs.

(d) The Board shall consult with interested persons respecting the activities of the Board under this section and as part of such consultation shall provide the opportunity for the submission of oral views.

(e) The Board shall submit to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives an annual report---

(1) identifying the drugs which have been designated under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition,

(2) describing the activities of the Board, and

(3) containing the results of the evaluations carried out by the Board.

The Director of the National Institutes of Health and the Administrator of the Alcohol, Drug Abuse, and Mental Health Administration shall submit to the Board for inclusion in the annual report a report on the rare disease and condition research activities of the Institutes of the National Institutes of Health and the Alcohol, Drug Abuse, and Mental Health Administration; the Secretary of the Treasury shall submit to the Board for inclusion in the annual report a report on the use of the credit against tax provided by section 44H of the Internal Revenue Code of 1954; and the Secretary of Health and Human Services shall submit to the Board for inclusion in the annual

report a report on the program of assistance under section 5 of the Orphan Drug Act for the development of drugs for rare diseases and conditions. Each annual report shall be submitted by June 1 of each year for the preceding calendar year.